



IN THE UNITED STATES PATENT AND TRADEMARK OF

In re of the Application of

Stephen Michnick et al

Serial Number: 09/603,885

Filed: June 26, 2000

For: AN IN VIVO LIBRARY VERSUS
LIBRARY SELECTION OF OPTIMIZED
PROTEIN-PROTEIN INTERACTIONS
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Group Art Unit: 1627 Examiner: P. Padmashri

ELECTION WITH TRAVERSE UNDER 37 CFR 1.143

Hon. Commissioner of Patents and Trademarks Washington, D.C. 20231

Dear Sir:

Responsive to the Office Action dated July 16, 2002, with the period for response extended one month (a check in the amount of \$55.00 is enclosed for a month extension of time) and in compliance with 37 CFR 1.143, Applicant provisionally elects with traverse the Group I invention (claims 1, 3-4 and 9) directed to a method for identifying an interacting set of molecules comprising: (A) generating fragments of a reporter molecule which have a directly or indirectly detectable activity when associated; (B) coupling first fragments to members of a first panel of molecules; (C) coupling second fragments to members of a second panel of molecules; (D) mixing the products of (B) and (C); (E) directly or indirectly testing for said activity; and (F) identifying the panel members whose interaction resulted in said activity and which thus form an interacting set.

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For purposes of Examination and as requested by the Examiner, the following species are selected:

- (i) As the reporter molecule applicant elects fragments of the enzyme mDFHR (murine enzyme dihydrofolate reductase) as shown in Example 1;
- (ii) The detectable activity clearly is reconstitution of enzymatic activity. See page 3, lines 6-10;
 - (iii) The first panel molecules are the WinZip A1 peptides, See figure 2;
- (iv) The second panel of molecules are the WinZip B1 interacting peptides, See figure 2; and
 - (v) The library of molecules is a library of peptides or proteins.

Applicants respectfully request that the Examiner unify all the Groups for one simple reason: The invention strategy is based on the folding of the murine enzyme DHFR from complementary fragments. It is clear to applicant that the claims of the present invention which are not unduly multiplied uses the complementation of DHFR fragments. Products, assays and methods should be searched simultaneously.

The restriction requirement is respectfully traversed. 35 USC 121 is permissive, not mandatory, and accordingly MPEP 808 requires not only full clarification of the reasons why inventions as claimed are independent and distinct but also the reasons for insisting on restriction therebetween.

The Examiner has restricted the 17 claims as filed (considering new Director Rogan's grandiose plan for the 21st century – it appears to applicant that the number of claims is exceptionally reasonable for Examination all at once) into IX groups.

The restriction into nine groups does not appear reasonable given the total number of claims the Examiner has to consider on the merits. The Examiner is urged to consider all claims as filed without restriction.

Furthermore, the Commissioner's notices appearing in 934 OG 2 and 922 OG 1016 urge examination of an entire application on the merits if this can be made without serious burden on the Examiner, even in cases which includes claims to distinct or independent inventions, which frankly in this application is not the case since DHFR fragment complementation as applied to the instant application can be searched simultaneously. Applicant believes that the entire invention as claimed can be examined without serious burden to the Examiner.

Applicant queries as to why a restriction requirement was given by the Examiner.

Applicants' request reconsideration of the restriction requirement. Additionally, Applicant believes that there is unity of invention as required by M.P.E.P. 800. Also, with the advent of electronic database searching, how can there be undue burden on the Examiner to conduct a search relating to the present invention as embodied in claims 1-17 as originally filed?. The above does not appear to be a big burden.

Applicant respectfully requests and urges the Examiner to examine the present application as a whole. Because of the new GATT rules, it is respectfully requested that this application be examined in its entirety since it is not clear still as of 2002, what the patent office policy will be regarding divisional practice. Certainly, applicant feels strongly that if the patent office restricts an application, applicant is entitled to twenty years for each divisional application from the filing date of each divisional, not the earliest filing date

of the original application, especially if the patent office is telling applicant that he has nine distinct inventions in the current application.

Also, it is noted that the restriction requirement fails to clearly state that the many inventions are independent and distinct, rather, only distinct. If, the Patent and Trademark Office intends to divide the present application into a plurality of Examiner-determined inventions and restrict prosecution of the present application to one aspect of the subject matter which Applicant regards as his invention, equity requires that the factual basis for so holding be clearly delineated so that the record will reflect if such a requirement is proper under 35 USC 121.

The importance of the written record clearly setting forth the reasons upon which a restriction requirement is based, particularly with respect to claims to a compound or composition held patentably distinct by the Patent and Trademark Office over method of use claims, is increasingly apparent from a brief filed by the Justice Department in <u>U.S. v. Union Carbide Corp.</u>, an antitrust action in the U.S. District Court for Northern California seeking to invalidate U.S. Patent 3,009,855 on the insecticide "Sevin". In that case, the Patent and Trademark Office had insisted that the original application, claiming both a product and method of use, be restricted and merely alleged that the two constituted "distinct" inventions. Applicants retained product claims in the original application and canceled method claims which were presented in a divisional application. Some 20+ years later, the Justice Department argued in its brief that the restriction requirement was clearly not authorized under 35 USC 121, since the statue imposes the dual criteria that restrictable inventions must be both independent and distinct, stating in its brief:

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...it is clear that the product carbaryl and its only disclosed use, e.g., killing insects,

are not "independent and distinct" inventions. Since the first application expressly

discloses how to use carbaryl as an insecticide in order to meet the statutory

requirements for patentability, it cannot properly be said there is "no disclosed

relationship" between the product carbaryl and its disclosed use as an insecticide. Nor

can it be correctly said that the product carbaryl is "unconnected in design, operation or

effect" with its use to kill insects. Thus it is clear that the restriction requirement which

was imposed on the first application lacked authority under 35 USC 121 because that

application did not claim "two or more independent and distinct inventions"...

In view of the above, reconsideration and withdrawal or at least clarification of the

restriction requirement and an early action on the merits are courteously requested.

Respectfully submitted,

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Date: September 16, 2002

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